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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,873	01/21/2004	Nicholas M. Valiante	PP20203.003	5927

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
02/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,873	VALIANTE, NICHOLAS M.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-11,18 and 20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17, 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim(s) 1-31 are pending. Claim(s) 1-11, 18, 20-31 have been withdrawn. Claim(s) 12 and 14 have been amended. Claim(s) 12-17, 19 are examined herein.

Applicant's amendments have rendered the 103(a) rejection of the last Office Action moot, therefore hereby withdrawn. The following new rejection will now apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-17, 19 are rejected under 35 U.S.C. 103(a) as being obvious over Baker et al. (US Patent 5,441,955) in view of Colston et al. (US Patent 7,122,195 B2).

The instant claims are directed to a composition comprising a tryptanthrin compound (No. 1001) and an antigen.

Baker et al. teach the tryptanthrin compound of No. 1001 in the applicant's specification (col. 20, lines 22-33) as part of an antimicrobial composition (abstract). Furthermore, this tryptanthrin compound can be administered with an adjuvant (col. 12, lines 37-42). What's more, Baker et al. teach that tryptanthrin can be administered in combination with one or more other agents used in the treatment of pathogenic mycobacterial infections. Representative agents used for the treatment of mycobacterial tuberculosis include, for example, isoniazid, rifampin, pyrazinamide, ethambutol, rifabutin, streptomycin, and ciproflaxin (col. 13, lines 35-43). Examiner would like to point out that mycobacterial tuberculosis is a common cause of bacterial meningitis (meningococcus infection). Moreover, Bacillus of Calmette and Guérin (BCG) is a vaccine against tuberculosis caused by mycobacterial tuberculosis.

Examiner reminds Applicant that the limitation "for enhancing an immune response" in claim 12 is considered preamble or intended use, since the claims are drawn to a composition, therefore will given little patentable weight.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Examiner further reminds Applicant that the limitations "immunogenic" and "providing an enhanced immune response to the antigen than provided without the tryptanthrin compound adjuvant" in claim 12 as well as "enhances an immune response to the antigen and the immune response is the cellular production of one or more cytokines" in claim 15 will be given little patentable weight since a composition and its properties are inseparable.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable

weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Baker et al., however fails to disclose a specific combination of the tryptanthrin compound (No. 1001) and an antigen disclosed in claim 14.

Colston et al. teach that recA mutant mycobacteria, particularly mutants of mycobacterial species which are members of Mycobacterium tuberculosis, are useful as vaccines for the treatment of a range of disorders, including tuberculosis (abstract). Colston et al. teach that this invention may be used as an antigen delivery system in the treatment of any disease, such as pathogenic infection, which is ameliorated by an immune response against a particular antigen. Suitable antigens include viral, protozoal, tumour cell, bacterial, and fungal antigens, for example an antigen from the Tetanustoxin, and Diphtheriatoxin. Such an antigen may be useful in the treatment of tetanus and diphtheria (col. 4, line 51 to col. 5, line 14).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the tryptanthrin compound (No. 1001) as disclosed by Baker et al. with the composition comprising antigens associated with tetanus or diphtheria as disclosed by Colston et al.

A person of ordinary skill in the art would have been motivated to combine the tryptanthrin compound (No. 1001) with a composition comprising antigens associated with tetanus or diphtheria because: (1) both Baker and Colston are analogous are since both teach the treatment of pathogenic mycobacterial infections, for example tuberculosis; (2) Baker teaches that the tryptanthrin compound can be administered with an adjuvant or another agent used in the treatment of pathogenic mycobacterial infections; (3) Baker teaches the use of antigens such as BCG in a vaccine against tuberculosis; (4) Colston teaches an antigen delivery system in the treatment of any disease, such as pathogenic infection, which is ameliorated by an immune response against a particular antigen; and (5) Colston specifically discloses suitable antigens, such as include viral, protozoal, tumour cell, bacterial, and fungal antigens, for example antigens from the Tetanustoxin and Diphtheriatoxin.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

The Valiante Declaration under 37 CFR 1.132 filed 10/31/2007 is insufficient to overcome the rejection of claims 12-17, 19 based upon Baker et al. (US Patent 5,441,955) in view of Colston et al. (US Patent 7,122,195 B2).

It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

A new rejection based on Baker in view of Colston has been made, to which the arguments or Declaration does not directly address. The Valiante Declaration simply states that the tryptanthrin compound can be effective in generating an immune response as viewed in Table 1. The ability to stimulate TNF-alpha production is viewed as unexpected based on previously known properties of tryptanthrin. Examiner does not view this as unexpected properties since tryptanthrin is a known compound. Furthermore, the claims and rejection are based on the combination of tryptanthrin compound and an antigen in claim 14. There is no factual data, commensurate with the scope of the claims to overcome the new obviousness rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER